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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and TAKEDA IRELAND LIMITED,

Plaintiffs,

v.

TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC.,

Defendants.

Civil Action No. ____________________

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A."), Takeda Pharmaceuticals America, Inc. ("Takeda America"), and Takeda Ireland Limited ("Takeda Ireland") (collectively, "Plaintiffs") by their undersigned attorneys, and for their complaint against Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (together, "Torrent"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Torrent's filing of Abbreviated New Drug Application ("ANDA") Nos. 21-0159, 21-0160 and 21-0161 with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market generic versions of the pharmaceutical drug products Nesina®, Kazano®, and Oseni® prior to the expiration of U.S. Patent Nos. 7,807,689 ("the '689 patent"), 8,173,663 ("the '663 patent"), 8,288,539 ("the '539 patent"), and 8,900,638 ("the '638 patent") (collectively, the "patents-in-suit").

THE PARTIES

2. Plaintiff Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products.

3. Plaintiff Takeda Japan is the owner of record and assignee of all of the patents-in-suit.

4. Plaintiff Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda

U.S.A. is involved in the research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application ("NDA") Nos. 22-271 (Nesina®), 22-426 (Oseni®), and 203-414 (Kazano®).

5. Plaintiff Takeda America is a Delaware corporation. It is a wholly owned subsidiary of Takeda U.S.A., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Takeda America has the right to sell Nesina®, Oseni®, and Kazano® in the United States.

6. Plaintiff Takeda Ireland is a company incorporated under the laws of Ireland. It is a wholly owned subsidiary of Takeda Japan and maintains its registered office at Bray Business Park, Kilruddery, Co. Wicklow, Ireland. Takeda Ireland is the exclusive licensee of the patents-in-suit.

7. Upon information and belief, Torrent Pharmaceuticals Ltd. is a company organized under the laws of India, having its principal place of business at Off. Ashram Road, Ahmedabad, Gujarat 380009, India.

8. Upon information and belief, Torrent Pharma Inc. is a Delaware corporation, having its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

9. Upon information and belief, Torrent Pharma Inc. is a wholly owned subsidiary of Torrent Pharmaceuticals Ltd.

10. Upon information and belief, Torrent Pharmaceuticals Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in New Jersey and throughout the United States through at least Torrent Pharma Inc.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Torrent because, *inter alia*, Torrent has a presence in New Jersey (including Torrent Pharma Inc.'s principal place of business), Torrent has conducted business in New Jersey, Torrent has availed itself of the rights and benefits of New Jersey law, Torrent has purposefully availed itself of the privilege of conducting business in New Jersey, Torrent has previously consented to personal jurisdiction in this Court, Torrent intends to sell its products in the State of New Jersey upon approval of ANDA Nos. 21-0159, 21-0160, and/or 21-0161, and Torrent has engaged in systematic and continuous contacts with the State of New Jersey.

13. Upon information and belief, (i) Torrent is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through its subsidiaries, agents, and/or alter-egos, that Torrent manufactures, distributes, markets, and sells throughout the United States and in this Judicial District; (ii) Torrent purposefully has conducted business and continues to conduct business directly, and/or through its subsidiaries, agents, and/or alter-egos in this Judicial District; (iii) this Judicial District is likely a destination of Torrent's products that are the subject of this lawsuit; and (iv) Torrent Pharma Inc. maintains its principal place of business and its administrative offices in this Judicial District.

14. Torrent has stipulated and/or consented to personal jurisdiction before this Court in other patent cases, including: *Takeda GmbH, et al. v. Torrent Pharma Inc., et al.*, Civil Action No. 15-3375 (D.N.J. filed May 15, 2015), *Takeda GmbH, et al. v. Torrent Pharma Inc., et al.*, Civil Action No. 16-2091 (D.N.J. filed April 13, 2016), *Otsuka Pharmaceutical Co., Ltd. v.*

Torrent Pharmaceuticals Limited, et al., Civil Action No. 14-4671 (D.N.J. filed July 25, 2014), *Otsuka Pharmaceutical Co., Ltd. v. Torrent Pharmaceuticals Limited*, Civil Action No. 14-1078 (D.N.J. filed February 18, 2014). Furthermore, Torrent asserted counterclaims in at least some of these cases, thus availing itself of the benefits and protections of the laws of New Jersey and its court system.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

16. On October 5, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '689 patent, entitled "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of the inventors Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, and Luckner G. Ulysse. A copy of the '689 patent is attached hereto as Exhibit A.

17. Takeda Japan is the owner of all right, title, and interest in the '689 patent.

18. On May 8, 2012, the USPTO duly and lawfully issued the '663 patent, entitled "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of inventors Jun Feng, Stephen L. Gwaltney, Jeffrey A. Stafford, Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, Jonathon S. Salsbury, and Luckner G. Ulysse. A copy of the '663 patent is attached hereto as Exhibit B.

19. Takeda Japan is the owner of all right, title, and interest in the '663 patent.

20. On October 16, 2012, the USPTO duly and lawfully issued the '539 patent, entitled "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of inventors Jun Feng, Stephen L. Gwaltney, Jeffrey A. Stafford, Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, Jonathon S. Salsbury, and Luckner G. Ulysse. A copy of the '539 patent is attached hereto as Exhibit C.

21. Takeda Japan is the owner of all right, title, and interest in the ’539 patent.

22. On December 2, 2014, the USPTO duly and lawfully issued the ’638 patent, entitled “Solid Preparation Comprising Alogliptin and Metformin Hydrochloride,” to Takeda Japan as assignee of inventors Kazumichi Yamamoto and Hiroyoshi Koyama. A copy of the ’638 patent is attached hereto as Exhibit D.

23. Takeda Japan is the owner of all right, title, and interest in the ’638 patent.

Takeda Drug Products

24. Takeda U.S.A. holds approved NDA No. 22-271 for oral tablets containing 6.25 mg, 12.5 mg, and 25 mg of alogliptin benzoate, sold under the trade name Nesina®.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ’689 patent, the ’663 patent, and the ’539 patent are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to Nesina®.

26. Takeda U.S.A. holds approved NDA No. 22-426 for oral tablets containing alogliptin benzoate (12.5 mg/ 25 mg) and pioglitazone hydrochloride (15 mg/ 30 mg/ 45 mg), sold under the trade name Oseni®.

27. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ’689 patent, the ’663 patent, and the ’539 patent are listed in the Orange Book with respect to Oseni®.

28. Takeda U.S.A. holds approved NDA No. 203-414 for oral tablets containing alogliptin benzoate (12.5 mg) and metformin hydrochloride (500 mg/ 1000 mg), sold under the trade name Kazano®.

29. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ’689 patent, the ’663 patent, the ’539 patent, and the ’638 patent are listed in the Orange Book with respect to Kazano®.

Torrent's FDA Submissions

30. Upon information and belief, Torrent submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 335(j) (ANDA No. 21-0159), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Nesina® in the form of oral tablets containing 6.25 mg, 12.5 mg, and 25 mg of alogliptin benzoate ("Torrent's Alogliptin Generic Product"), prior to the expiration of the '689, '663, and '539 patents.

31. Torrent's ANDA No. 21-0159 relies upon the Nesina® NDA and, according to Torrent, contains the required data with respect to the bioavailability or bioequivalence of Torrent's Alogliptin Generic Product to Nesina®.

32. Takeda received letters from Torrent, dated April 3, 2017, with attached memoranda (collectively, "Torrent's Alogliptin Notification"), stating that Torrent included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '689, '663, and '539 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Torrent's Alogliptin Generic Product (the "Alogliptin Paragraph IV certification"). Thus, Torrent is seeking approval of its proposed Alogliptin Generic Product prior to the expiration of the '689, '663, and '539 patents. Plaintiffs are filing this complaint within the 45-day interval from receipt of Torrent's Alogliptin Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of Torrent's ANDA No. 21-0159 and Alogliptin Paragraph IV certification.

33. Upon information and belief, Torrent submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 335(j) (ANDA No. 21-0160), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Kazano® in the form of oral tablets containing 12.5 mg of

alogliptin benzoate and 500 mg/1000 mg of metformin hydrochloride ("Torrent's Alogliptin-Metformin Generic Product"), prior to the expiration of the '689, '663, '539, and '638 patents.

34. Torrent's ANDA No. 21-0160 relies upon the Kazano® NDA and, according to Torrent, contains the required data with respect to the bioavailability or bioequivalence of Torrent's Alogliptin-Metformin Generic Product to Kazano®.

35. Takeda received letters from Torrent, dated March 29, 2017, with attached memoranda (collectively, "Torrent's Alogliptin-Metformin Notification"), stating that Torrent included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '689, '663, '539, and '638 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Torrent's Alogliptin-Metformin Generic Product (the "Alogliptin-Metformin Paragraph IV certification"). Thus, Torrent is seeking approval of its proposed Alogliptin-Metformin Generic Product prior to the expiration of the '689, '663, '539, and '638 patents. Plaintiffs are filing this complaint within the 45-day interval from receipt of Torrent's Alogliptin-Metformin Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of Torrent's ANDA No. 21-0160 and Alogliptin-Metformin Paragraph IV certification.

36. Upon information and belief, Torrent submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 335(j) (ANDA No. 21-0161), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Oseni® in the form of oral tablets containing 12.5 mg/25 mg of alogliptin benzoate and 15 mg/30 mg/45 mg of pioglitazone ("Torrent's Alogliptin-Pioglitazone Generic Product"), prior to the expiration of the '689, '663, and '539 patents.

37. Torrent's ANDA No. 21-0161 relies upon the Oseni® NDA and, according to Torrent, contains the required data with respect to the bioavailability or bioequivalence of Torrent's Alogliptin-Pioglitazone Generic Product to Oseni®.

38. Takeda received letters from Torrent, dated March 24, 2017, with attached memoranda (collectively, "Torrent's Alogliptin-Pioglitazone Notification"), stating that Torrent included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '689, '663, and '539 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Torrent's Alogliptin-Pioglitazone Generic Product (the "Alogliptin-Pioglitazone Paragraph IV certification"). Thus, Torrent is seeking approval of its proposed Alogliptin-Pioglitazone Generic Product prior to the expiration of the '689, '663, and '539 patents. Plaintiffs are filing this complaint within the 45-day interval from receipt of Torrent's Alogliptin-Pioglitazone Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of Torrent's ANDA No. 21-0161 and Alogliptin-Pioglitazone Paragraph IV certification.

COUNT ONE: INFRINGEMENT OF THE '689 PATENT

39. Plaintiffs repeat and reallege the allegations of paragraphs 1–38 as though fully set forth herein.

40. Submission of ANDA Nos. 21-0159, 21-0160, and 21-0161 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of oral tablets containing alogliptin benzoate (6.25 mg, 12.5 mg, 25 mg), a combination of alogliptin benzoate (12.5 mg) and metformin hydrochloride (500 mg/1000 mg), and a combination of alogliptin benzoate (12.5 mg/25 mg) and pioglitazone (15 mg/30 mg/45 mg), respectively, prior to the expiration of the '689 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

41. Unless enjoined by this Court, upon FDA approval, Torrent will induce infringement of the ’689 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Torrent will intentionally encourage acts of direct infringement with knowledge of the ’689 patent and knowledge that its acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval, Torrent will contributorily infringe the ’689 patent under 35 U.S.C. § 271(c). Upon information and belief, Torrent has had and continues to have knowledge that Torrent’s Alogliptin Generic Product, Torrent’s Alogliptin-Metformin Generic Product, and Torrent’s Alogliptin-Pioglitazone Generic Product (collectively, “Torrent’s Generic Products”) are especially made or especially adapted for a use that infringes the ’689 patent and that there are no substantial non-infringing uses for Torrent’s Generic Products.

43. Torrent does not contest infringement of claims 1, 3-4, 9, 11-15, 18, 25-27, 30-34, 39-43, and 49 of the ‘689 patent in Torrent’s Alogliptin Notification, Torrent’s Alogliptin-Metformin Notification or Torrent’s Alogliptin-Pioglitazone Notification (collectively, “Torrent’s Notifications). If Torrent had a factual or legal basis to contest infringement of claims 1, 3-4, 9, 11-15, 18, 25-27, 30-34, 39-43, and 49 of the ’689 patent, it was required by applicable regulations to state such a basis in Torrent’s Notifications. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

44. Torrent’s actions, including its reliance on the purported defenses and statements set forth in Torrent’s Notifications regarding the ’689 patent, warrant a finding that this case is

an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

45. Plaintiffs will be substantially and irreparably harmed if Torrent's infringement of the '689 patent is not enjoined.

46. Plaintiffs do not have an adequate remedy at law.

COUNT TWO: INFRINGEMENT OF THE '663 PATENT

47. Plaintiffs repeat and reallege the allegations of paragraphs 1–46 as though fully set forth herein.

48. Submission of ANDA Nos. 21-0159, 21-0160, and 21-0161 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of oral tablets containing alogliptin benzoate (6.25 mg, 12.5 mg, 25 mg), a combination of alogliptin benzoate (12.5 mg) and metformin hydrochloride (500 mg/1000 mg), and a combination of alogliptin benzoate (12.5 mg/25 mg) and pioglitazone (15 mg/30 mg/45 mg), respectively, prior to the expiration of the '663 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

49. Unless enjoined by this Court, upon FDA approval, Torrent will induce infringement of the '663 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Torrent will intentionally encourage acts of direct infringement with knowledge of the '663 patent and knowledge that its acts are encouraging infringement.

50. Unless enjoined by this Court, upon FDA approval, Torrent will contributorily infringe the '663 patent under 35 U.S.C. § 271(c). Upon information and belief, Torrent has had and continues to have knowledge that Torrent's Generic Products are especially made or especially adapted for a use that infringes the '663 patent and that there are no substantial non-infringing uses for Torrent's Generic Products.

51. Torrent does not contest infringement of claims 1, 4, 6-10, 12, 14-21, 27, and 29 of the ’663 patent in Torrent’s Notifications. If Torrent had a factual or legal basis to contest infringement of claims 1, 4, 6-10, 12, 14-21, 27, and 29 of the ’663 patent, it was required by applicable regulations to state such a basis in Torrent’s Notifications. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

52. Torrent’s actions, including its reliance on the purported defenses and statements set forth in Torrent’s Notifications regarding the ’663 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

53. Plaintiffs will be substantially and irreparably harmed if Torrent’s infringement of the ’663 patent is not enjoined.

54. Plaintiffs do not have an adequate remedy at law.

COUNT THREE: INFRINGEMENT OF THE ’539 PATENT

55. Plaintiffs repeat and reallege the allegations of paragraphs 1–54 as though fully set forth herein.

56. Submission of ANDA Nos. 21-0159, 21-0160, and 21-0161 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of oral tablets containing alogliptin benzoate (6.25 mg, 12.5 mg, 25 mg), a combination of alogliptin benzoate (12.5 mg) and metformin hydrochloride (500 mg/1000 mg), and a combination of alogliptin benzoate (12.5 mg/25 mg) and pioglitazone (15 mg/30 mg/45 mg), respectively, prior to the

expiration of the ’539 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. Unless enjoined by this Court, upon FDA approval, Torrent will induce infringement of the ’539 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Torrent will intentionally encourage acts of direct infringement with knowledge of the ’539 patent and knowledge that its acts are encouraging infringement.

58. Unless enjoined by this Court, upon FDA approval, Torrent will contributorily infringe the ’539 patent under 35 U.S.C. § 271(c). Upon information and belief, Torrent has had and continues to have knowledge that Torrent’s Generic Products are especially made or especially adapted for a use that infringes the ’539 patent and that there are no substantial non-infringing uses for Torrent’s Generic Products.

59. Torrent does not contest infringement of claims 1-3, 5-9, 11, 13-18, 22-23, 29, and 31 of the ’539 patent in Torrent’s Notifications. If Torrent had a factual or legal basis to contest infringement of claims 1-3, 5-9, 11, 13-18, 22-23, 29, and 31 of the ’539 patent, it was required by applicable regulations to state such a basis in Torrent’s Notifications. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

60. Torrent’s actions, including its reliance on the purported defenses and statements set forth in Torrent’s Notifications regarding the ’539 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

61. Plaintiffs will be substantially and irreparably harmed if Torrent's infringement of the '539 patent is not enjoined.

62. Plaintiffs do not have an adequate remedy at law.

COUNT FOUR: INFRINGEMENT OF THE '638 PATENT

63. Plaintiffs repeat and reallege the allegations of paragraphs 1–62 as though fully set forth herein.

64. Submission of ANDA No. 21-0160 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of oral tablets containing a combination of alogliptin benzoate (12.5 mg) and metformin hydrochloride (500 mg/1000 mg) prior to the expiration of the '638 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

65. Unless enjoined by this Court, upon FDA approval, Torrent will induce infringement of the '638 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Torrent will intentionally encourage acts of direct infringement with knowledge of the '638 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval, Torrent will contributorily infringe the '638 patent under 35 U.S.C. § 271(c). Upon information and belief, Torrent has had and continues to have knowledge that Torrent's Alogliptin-Metformin Generic Products is especially made or especially adapted for a use that infringes the '638 patent and that there are no substantial non-infringing uses for Torrent's Alogliptin-Metformin Generic Product.

67. Torrent's actions, including its reliance on the purported defenses and statements set forth in Torrent's Alogliptin-Metformin Notification regarding the '638 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

68. Plaintiffs will be substantially and irreparably harmed if Torrent's infringement of the '638 patent is not enjoined.

69. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Takeda Japan, Takeda U.S.A., Takeda America, and Takeda Ireland respectfully request the following relief:

A. A Judgment be entered that Torrent has infringed the '689, '663, '539, and '638 patents;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Torrent, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering to sell, or selling Torrent's Generic Products within the United States, or importing Torrent's Generic Products into the United States, prior to the expiration of the patents-in-suit;

C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA Nos. 21-0159, 21-0160, and 21-0161 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the patents-in-suit, including any extensions;

D. If Torrent commercially manufactures, uses, offers to sell, or sells Torrent's Generic Products within the United States, or imports Torrent's Generic Products into the United States, prior to the expiration of the patents-in-suit including, any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: May 5, 2017

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 & 40.1, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 5, 2017

By: s/ Charles M. Lizza

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